

**Package leaflet: Information for the patient**

**UNOSEMIDE-10**

**(Furosemide Injection BP 10mg/ml)**

Furosemide

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

- a) What Unosemide-10 is and what it is used for
- b) What you need to know before you use Unosemide-10
- c) How to use Unosemide-10
- d) Possible side effects
- e) How to store Unosemide-10
- f) Contents of the pack and other information

**A) WHAT UNOSEMIDE-10 IS AND WHAT IT IS USED FOR**

Furosemide 10 mg/ml solution for injection/infusion contains the active substance furosemide.

Furosemide belongs to a group of medicines called diuretics. It is given if sufficient urine output is not achieved by oral administration of furosemide or if oral administration is not possible.

Furosemide is used:

- to treat fluid retention in the tissue (oedema) and/or accumulation of fluid in the abdomen (ascites) due to heart or liver disease;
- to treat fluid accumulation in the tissue (oedema) due to kidney disease;
- in the case of fluid accumulation in the lungs (pulmonary oedema) (e.g. in acute heart failure);
- in case of extremely high blood pressure (hypertensive crisis) in addition to other therapeutic measures.

**B) WHAT YOU NEED TO KNOW BEFORE YOU USE UNOSEMIDE-10**

**You should not be given Furosemide Injection if**

- you are allergic to furosemide or any of the other ingredients of this medicine (listed in section 6).  
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- you are allergic to amiloride, sulfonamides or sulphonamide derivatives, such as sulfadiazine or cotrimoxazole
- you have a low blood volume or are dehydrated (with or without accompanying low blood pressure)
- you have too little potassium or sodium in your blood (shown in blood test)
- you have severe liver problems (cirrhosis).
- you have already used furosemide in the past to treat failure to pass urine or kidney failure or if you have kidney failure that is due to medicines or chemicals that are prone to cause kidney or liver damage or if you have kidney failure due to underlying liver disorders
- you are not passing any water (urine) or you have been told by a doctor that you have kidney failure. In some types of kidney failure, it is still okay to have this medicine. Your doctor will be able to decide
- you have an illness called 'Addison's Disease'. This can make you feel tired and weak or if you are taking digitalis, used to treat heart problems.
- you have a disease called porphyria characterized by abdominal pain, vomiting or muscle weakness
- you are breast feeding.

## Warnings and precautions

Talk to your doctor or nurse before you are given Furosemide Injection

- if you are elderly, if you are on other medications which can cause drop in the blood pressure and if you have other medical conditions that are risks for the drop of blood pressure
- if you have low blood pressure or feel dizzy when you stand up
- if you feel dizzy or dehydrated. This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating
- if you have low blood levels of essential minerals like sodium or potassium or you have acid base imbalance in the body identified by blood tests
- if you have difficulty in passing water, for example because of an enlarged prostate gland (males only)
- if you have diabetes
- if you have gout (characterised by painful joints due to elevated uric acid levels)
- if you have kidney or liver problems
- if you have low blood protein levels (hypoproteinaemia) as this may reduce the effect of the drug and increase the risk of ear damage
- if you have raised levels of calcium in the blood; careful monitoring of fluids and electrolyte levels are recommended
- if you have a risk of fall in blood pressure; or in case of premature infants as they may be more prone to development of kidney stones
- if you are already on medicines like NSAIDs (used for inflammation and pain) or ACE inhibitors (medicines used to lower blood pressure)
- laboratory monitoring
- It is recommended to undergo regular monitoring of blood levels for sodium, potassium, kidney function tests (blood urea nitrogen and creatinine levels), glucose, magnesium, calcium, chloride bicarbonate and uric acid
- regular monitoring is required to check for occurrence of blood dyscrasias (abnormal or imbalance in blood components), liver damage or any symptom that may occur particularly to you
- if you are an elderly patient with dementia and are also taking risperidone.

You must not be given Furosemide Injection if you are planning to undergo procedure that includes the use of radiocontrast (as taking Furosemide Injection may increase the risk for kidney damage).

## Other medicines and Unosemide-10

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Your doctor may need to change your dose and/or to take other precautions if you are taking one of the following medicines:

- Aliskiren – used to treat high blood pressure

Tell your doctor:

- if you are taking the below medicines as the dose of these may need to be changed to avoid the risk of excessive lowering of blood pressure. Other blood pressure lowering agents (cardiac glycosides eg digoxin, other diuretics that help you pass more urine; or other blood pressure lowering agents)
- if you are taking any drugs that can be harmful to your kidneys
- if you have low levels of potassium or magnesium in your blood indicated by the blood counts.

A large number of drugs can interact with furosemide which can significantly alter their effects.

These drugs include:

- medicines such as ramipril, enalapril, perindopril (called ‘ACE inhibitors’) or losartan, candesartan, irbesartan (called ‘angiotensin II receptor antagonists’)
- anti-psychotics (medicines used to treat mental disorders) such as tricyclic antidepressants, hypnotics and anxiolytics (e.g pimozone, amisulpride, sertindole or phenothiazines), risperidone used to treat dementia
- medicines for high blood pressure or heart problems (uneven heart beat) such as calcium channel blockers, beta blockers, clonidine, moxonidine, sodium nitroprusside, amiodarone, disopyramide,
- flecainide, minoxidil, lidocaine, prazosin, diazoxide, methyl dopa, sotalol and mexiletine
- cardiac glycosides (drugs used to improve heart function) eg. digoxin which is used to treat heart failure. Your doctor may need to change the dose of your medicine
- thymoxamine or hydralazine used to lower blood pressure
- metolazone- medicine used to pass more urine

- nitrates- used to lower blood pressure
- lithium- used for mental illness
- sucralfate- this drug may decrease the absorption of furosemide
- NSAIDs- drugs used to treat pain and inflammation (eg. indomethacin, ketorolac)
- salicylates (eg aspirin)
- antibiotics belonging to class of aminoglycosides, polymixins or vancomycin; as there may be a risk of ear or kidney damage, low sodium levels with trimethoprim, and cephalosporins e.g. cefalexin and ceftriaxone
- medicines used to treat depression (eg. TCA or MAOIs)
- medicines used to treat diabetics.
- medicines used to treat epilepsy (eg carbamazepine, phenytoin)
- anti-histamines (medicines used to treat allergies)
- anti-fungals e.g. amphotericin (risk of potassium loss or renal damage indicated with furosemide)
- choral hydrate or triclofos (drugs used to treat anxiety)
- drugs used to treat Attention Deficit Hyperactivity Disorder (ADHD) like e.g. atomoxetine, amphetamines
- steroids (used to treat inflammation)
- liquorice; increased risk of loss of potassium with furosemide
- platinum containing compounds like cisplatin- used to treat cancers (increased risk of kidney damage with furosemide)
- methotrexate- increase chance of furosemide toxicity
- levodopa- used to treat parkinson's disease (increased risk of lowering of blood pressure with furosemide)
- medicines that modify immune system- (eg aldesleukin or ciclosporin)
- medicines used as muscle relaxants like baclofen, tizanidine or curare like drugs
- birth control Pills or oestrogen containing drugs may block the effect of furosemide if taken concurrently
- progesterone containing drugs (drospiridone) may lead to reduced blood potassium levels if taken with furosemide
- medicines such as alprostadil, used to treat erectile dysfunction (impotency)
- theophylline used for wheezing or difficulty in breathing
- probenecid used for treatment of gout
- medicines used as general anaesthetics to induce unconsciousness. If you are going
- to have an anaesthetic please ensure that the doctor or nurse knows you are taking furosemide
- laxatives- drugs used to relieve constipation e.g. bisacodyl, senna
- medicines for asthma when given in high doses such as salbutamol, terbutaline sulphate,
- salmeterol, formoterol or bambuterol
- medicines used to treat blocked noses, such as ephedrine and xylometazoline
- aminoglutethimide used to treat breast cancer.

### **Furosemide Injection with alcohol**

- avoid consumption of alcohol with Furosemide Injection as it may lead to excessive lowering of blood pressure.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

#### **Pregnancy**

- Furosemide passes through the placenta and hence should not be given during pregnancy unless doctor feels it extremely necessary. If it is given in cases of swelling or water retention, the growth of the baby must be regularly monitored.

#### **Breast-feeding**

- Furosemide passes into the milk and may inhibit secretion of milk. Hence it should be avoided in breast feeding women.

### **Driving and using machines**

Furosemide may cause some patients to be less alert which could interfere with the ability to drive or to operate machines. If you notice that you are not as alert as usual, do not drive or operate machinery and ask your doctor for advice.

### **Unosemide-10 contains sodium**

Furosemide 10mg/ml Solution for Injection contains less than 1mmol sodium (23mg) per 2ml.

### **C) HOW TO USE UNOSEMIDE-10**

Furosemide Injection will always be given to you by a doctor or nurse. This is because it can only be given by injection. It may be given by injecting the solution into a muscle (intramuscular) or by injecting it slowly into a vein (intravenous). Your doctor will decide on the most suitable dose for you, and how the medicine will be given. The dosage and frequency of repeated doses may change depending on how you respond to treatment.

#### **The recommended dose is:**

**Adults:** The initial dose may vary from 20 mg to 250 mg depending on how you respond.

**Elderly:** Furosemide is generally cleared from the body more slowly in the elderly. If you are elderly, your doctor may decide to start with a low dose and increase the dose gradually according to your response.

**Use in Children:** The doctor will decide on the dosage, depending on how severely the kidneys are affected and on the response to initial doses. Whilst you are receiving treatment with this medicine, your doctor may want to take blood for testing which will show if you have the right balance of fluid and chemicals in the body. If you have any further questions on the use of this product, ask your doctor or nurse.

#### **If you think you have been given more Furosemide Injection than you should have**

As the injection will be administered by a doctor, it is unlikely that you will be given more than is necessary. However, if you think that you have been given too much, tell your doctor immediately.

#### **If you have missed an administration of Furosemide Injection.**

If you think you may have missed a dose, tell the doctor or nurse.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

### **D) POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the below mentioned side effects are observed please inform your doctor immediately

- allergic reactions such as itching, skin rash with severe itching and nettle rash, fever, allergic to light, severe allergic reaction with (high) fever, red patches on the skin, joint pain and/or inflammation of the eyes, "acute generalised exanthematous pustulosis (AGEP)", DRESS, (acute febrile drug eruption) characterized by severe acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots from bleeding in the skin
- sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back
- abnormal blood counts, severe changes in blood count and signs e.g. sore throat, mouth ulcers, fever, unexplained bruising or bleeding
- signs of kidney inflammation e.g. blood in the urine, pain in the lower back, rarely could also lead to acute kidney failure.
- signs of metabolic acidosis: chest pain, irregular heartbeat, nausea, vomiting, weakness.
- certain liver function disorders or increase in certain liver enzymes- a life-threatening form of unconsciousness
- shock (severe drop in blood pressure, extreme paleness, restlessness, weak fast pulse, clammy skin impaired consciousness) as a result of a sudden severe dilatation of the blood vessels due to allergy to certain substances.

**The other possible side effects are listed under headings of frequency, using the following categories:**

#### **Uncommon: may affect up to 1 in 100 people**

- blurred vision
- lowering of blood pressure, resulting in impaired concentration and reactions, light headedness, a feeling of pressure in the head, headache, dizziness, drowsiness, a feeling of weakness, visual disturbances, dry mouth and an inability to stand upright
- sensitivity to light (photosensitivity)
- feeling of tiredness
- dry mouth, thirst, disturbances of bowel like diarrhoea, constipation or vomiting
- raised blood levels of creatinine and urea
- deafness (sometimes irreversible)

#### **Rare: may affect up to 1 in 1,000 people**

- abnormal blood count (white blood cell deficiency) accompanied by an increased susceptibility to infection
- increase in certain substances (eosinophilic cells) in the blood
- a crawling sensation on the skin, itching or tingling without any reason
- hearing disorders & ringing in the ears. These disorders are usually temporary in nature.

- inflammation of a blood vessel
- fever
- muscle aches
- inability to control urination
- if you have a urinary tract obstruction, increased urine production may occur or worsen
- if you have a bladder disorder, enlarged prostate or narrowing of the ureters, urine production can stop suddenly
- minor mental disturbances.

**Very rare: may affect up to 1 in 10,000 people**

- anaemia (a condition characterised by shortage of red blood cells)
- very severe blood abnormality (white blood cell deficiency) accompanied by a sudden high fever, severe throat pain and ulcers in the mouth.

**Not known: frequency cannot be estimated from the available data**

- furosemide can cause an excessive depletion of bodily fluids (e.g. passing urine more often than normal) and minerals (sodium, potassium, magnesium, calcium). Symptoms that can occur are thirst, headache, confusion, muscle cramps, increased irritability of the muscles, muscular weakness, heart rhythm disturbances and gastrointestinal problems such as sensation of unease and discomfort in stomach with an urge to vomit or diarrhoea
- reduced concentration, light-headedness, sensations of pressure in the head, headache, dizziness, drowsiness, weakness, confusion

- if you have a shortage of sodium (sodium deficiency):

- cramp in the calf muscles
- loss of appetite
- listlessness
- feeling of weakness
- dizziness
- drowsiness
- confusion

- if you have a shortage of potassium (potassium deficiency):

- muscular weakness and the inability to contract one or more muscles (paralysis)
- increased excretion of urine
- heart problems

- in the case of severe potassium deficiency: interference with the function of the intestine or confusion which can result in coma

- if you have a shortage of magnesium and calcium (magnesium and calcium deficiency):

- increased irritability of the muscles
- heart rhythm disturbances

- during treatment with furosemide, the blood levels of some fats (cholesterol and triglyceride) may rise, but usually return to normal within 6 months

- changes in glucose test

- in the elderly, this can lead to a low blood volume, fluid depletion and thickening of the blood. This can cause clots to form in the blood

- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)

- bullous pemphigoid (an acute or chronic autoimmune skin disease, involving the formation of blisters, more appropriately known as bullae, at the space between the skin layers).

**Additional side effects in children**

Deposits of calcium salts in the kidneys or heart defects like patent ductus arteriosus have been reported in premature babies following treatment with furosemide.

**Reporting of side effects** If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

## **E) HOW TO STORE UNOSEMIDE-10**

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the ampoule or carton, after EXP:. The expiry date refers to the last day of that month.

Do not store above 30°C. Protect from light & moisture. Do not freeze

Keep the container in the outer carton in order to protect from light. If only part used, discard the remaining solution. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **F) CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Furosemide Injection contains**

The active substance is furosemide. The other ingredients are sodium chloride and sodium hydroxide in water for injections.

### **What Unosemide-10 looks like**

A colourless or almost colourless solution filled in amber colour glass ampoule with white ring on neck.

### **Contents of the pack**

Tray of 10 x 2 ml ampoules packed in monocarton along with pack insert.

### **Marketing Authorisation Holder:**

UNOSOURCE PHARMA LIMITED

503-504, 5th Floor, Hubtown Solaris, N.S. Phadke Marg, Andheri (east), Mumbai – 400 069, INDIA

### **Manufacturer:**

AKUMS DRUGS & PHARMACEUTICALS LTD.

Plot 2, 3, 4 & 5, Sector 6-A, IIE, Sidcul, Ranipur, District: Haridwar, Uttarakhand. INDIA.

### **Registration Details**

Not Applicable

**For any information about this medicine, please contact the Marketing Authorisation Holder.**

### **This leaflet was last approved in:**

Not Applicable